

ACTION: Notice of Emergency Rulemaking

SUBJECT: National Environmental Laboratory Accreditation Program Fees (R-70-00E)

PUBLIC PROCEEDINGS: Notice is hereby given that the California Department of Health Services will conduct written public proceedings, during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions relevant to the action described in this notice. Any written statements, arguments or contentions must be received by the Office of Regulations, Department of Health Services, 714 P Street, Room 1000, P.O. Box 942732, Sacramento, CA 94234-7320, by 5 p.m. on January 14, 2002, which is hereby designated as the close of the written comment period. It is requested but not required that written statements, arguments or contentions sent by mail or hand-delivered be submitted in triplicate.

Comments by FAX (916-657-1459) or email (regulation@dhs.ca.gov) must be received before 5:00 p.m. on the last day of the public comment period. All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes in the regulation text on which additional comments may be solicited.

CONTACTS: Inquiries concerning the action described in this notice may be directed to Charles E. Smith of the Office of Regulations at (916) 657-0730, or to the designated backup contact person, Allison Branscombe, at (916) 657-0692. Inquiries regarding the substance of the regulations may be directed to George Kulasingam, Ph.D., Chief of the Environmental Laboratory Accreditation Program, at (510) 540-2800. In any such inquiries, please identify the action by using the Department regulation control number **R-70-00E**.

Persons wishing to use the California Relay Service may do so at no cost. The telephone numbers for accessing this service are: 1-800-735-2929, if you have a TDD; or 1-800-735-2922, if you do not have a TDD.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW: California statutes govern the certification of environmental laboratories providing analytical data for regulatory purposes in California. These statutes were first adopted in 1988 (AB 3739, Chapter 894), as Chapter 7.5, Division 1, Part 2, Health and Safety Code, Sections 100825 through 100920 (formerly Sections 1010 through 1029). The statutes were amended in 1989, 1991, 1993, 1996, and 1999.

Regulations implementing the California statutes were first adopted as Section 64801 through 64827, Title 22, Division 4, Chapter 19, California Code of Regulations in 1994.

Section 100862, added to the Health and Safety Code (H&SC) by SB 1304 (Chapter 372, Statutes of 1999), specifically requires the establishment of fees to enable environmental laboratories in California to participate on a voluntary basis in the National Environmental Laboratory Accreditation Program (NELAP). NELAP accredited laboratories are required to fully support the NELAP accreditation costs through fees.

The Budget Act for 2000-2001 (AB 1740, Chapter 52, Statutes of 2000), Provision 2 to Item 4260-001-0001, provides that the department shall promulgate emergency regulations to adjust fees that otherwise would not be sufficient to support a fully fee supported program at least at the 95% level. Without the fees established in this regulation, the Department's NELAP accreditation program would not be supported by fees from the regulated laboratories at the required 95% level.

The Department has been approved by the United States Environmental Protection Agency's National Environmental Laboratory Accreditation Program to be the accrediting authority for the State of California.

California is required to maintain consistency with federal laws and regulations governing certain aspects of the activities of environmental testing laboratories. This proposed regulation change is consistent with the NELAP requirements and is not inconsistent with other related federal requirements.

The National Environmental Laboratory Accreditation Conference (NELAC) is the standard setting body whose standards and procedures serve as the basis for NELAP recognition and requirements. NELAC standards and procedures are specified in United States Environmental Protection Agency publication EPA 600/R-99/08, July 1999. There are no fees specified in the NELAC standards. The NELAC standards in Sections 4.1.6 and 6.2.1, provide that an accrediting authority, where required, shall establish the level and timing of fees to be paid by laboratories. However, California H&SC Code Section 100862 mandates the establishment of such fees to fully support the program.

Specifically, the Department has adopted regulation changes in Title 22, California Code of Regulations, summarized as follows:

Section 64860, in a new Article 16, was adopted to establish a schedule of fees for laboratories applying for NELAP accreditations. The new fees vary depending on the complexities of the fields of testing the laboratory is being approved to conduct. They are intended to reflect the increases in departmental workload costs incurred during the

evaluations and oversight of the capabilities of laboratories under the new accreditation program.

AUTHORITY: Sections 100830, 100835, and 100862, Health and Safety Code.

REFERENCE: Section 100825, Health and Safety Code.

FISCAL IMPACT ESTIMATE:

- A. Fiscal Effect on Local Government: No fiscal impact exists.
- B. Fiscal Effect on State Government: Expenditures are included in the FY 2001-02 Budget Bill for item 4260-001-0179.
- C. Fiscal Effect on Federal Funding of State Programs: No fiscal impact exists.
- D. All cost impacts, known to the Department at the time the notice of emergency action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the emergency action: Participation in the National Environmental Laboratory Accreditation Program (NELAP) is entirely voluntary. Laboratories choosing to participate in NELAP would incur the base fee of \$3000 and the appropriate fee for the fields of testing, ranging from \$750 to \$1,800.
- E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.

DETERMINATIONS: The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The Department has made an initial determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The Department has determined that the regulations would not significantly affect the following:

- (1) The creation or elimination of jobs within the State of California.
- (2) The creation of new businesses or the elimination of existing businesses within the State of California.

- (3) The expansion of businesses currently doing business within the State of California.

The Department has determined that the regulations may affect small businesses.

The Department has determined that the regulations will have no impact on housing costs.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS: The Department has prepared and has available for public review an initial statement of reasons for the emergency regulations, all the information upon which the emergency regulations are based, and the text of the emergency regulations. A copy of the initial statement of reasons and a copy of the text of the emergency regulations are available upon request by writing to the Office of Regulations at the address noted above, which address will also be the location of public records, including reports, documentation, and other material related to the emergency regulations (rulemaking file). Additionally, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations at the address noted above. Materials regarding the emergency regulations that are available via the Internet may be accessed at <http://www.dhs.ca.gov/regulation/>.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the emergency action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

ADDITIONAL STATEMENTS AND COMMENTS: In accordance with Government Code Section 11346.5(a)(13) the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action was taken or would be as effective and less burdensome to affected private persons than the emergency action.

No hearing has been scheduled; however any interested person or his or her duly authorized representative may request, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code Section 11346.8.

Sign language interpreting services at a public hearing or other reasonable accommodation will be provided upon request. Such request should be made no later than 21 days prior to the close of the written comment period, and addressed to the Office of Civil Rights within the Department of Health Services by phone (916-657-1411); FAX (916-657-0153); TDD (916-657-2861); or email (civilrights-ra@dhs.ca.gov).

DEPARTMENT OF HEALTH SERVICES

R-70-00E

Dated: November 1, 2001

Diana M. Bontá, R.N., Dr.P.H.
Director